



**GORILLA**  
CIRCUITS

# Quality Systems Manual

This manual was developed to support ISO 9001 elements

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## Revision History

<b>Revision</b>	<b>Description of Change</b>	<b>Author</b>	<b>Effective Date</b>
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05-03-17	Updates to various clause	J Melia	05-02-17
04-23-18	Updates to update ref Document Numbers – Refer to DCN 2681	J Melia	04/23/18

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## Statement of Commitment

The Quality Team, representing management of Gorilla Circuits is the approval authority for the Quality Management System operating throughout Gorilla Circuits. Names listed below signify approval and commitment to adhere to the contents of this manual.

Hershel Petty

President

Crescencio Gutierrez

GM - Fabrication

James Melia

Director of Quality

Ted Nguyen

GM - Assembly

This manual is issued to ensure compliance with corporate requirements to address quality in everything that we do. It is designed in alignment with the ISO 9001 requirements. It describes the Quality System deployed by Gorilla Circuits.

Issued By:

James Melia

Director of Quality

Management Representative

Date 01-31-2017

## Quality Policy, Vision, and Mission Statement

*GORILLA CIRCUITS*  
*Quality Policy*

*We are committed to meeting our customer's requirements and building a quality product. We accomplish this by:*

- \*Product Planning*
- \*Process Planning and Control*
- \*Open Communication*
- \*Continual Improvement*

### **Vision Statement:**

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- Gorilla Circuits wants to be the preferred provider of Printed Circuit Boards and Assemblies to the Electronics Industry.
- Gorilla Circuits wants to be recognized as a Customer oriented company that is known for its reliability and fair business practices.

## **Mission Statement:**

### INTERNAL

- Provide employees with the training, tools and authority necessary to enable them to provide our customers with the highest level of quality possible.
- Continuously improve products, processes and service through teamwork.
- Clearly communicate quality policies and goals throughout the organization. Each employee has the responsibility to comply with the policies and to ensure that goals are achieved.

### EXTERNAL

- We will communicate with our customer regularly to develop an understanding of their requirements and to appraise our performance in meeting those requirements.
- Purchase goods and services from sources that are committed to providing Gorilla Circuits with the highest level of quality. In addition, we will clearly communicate our requirements to suppliers, and will support them in attaining mutual quality goals.
- Immediately communicate the discovery of product or service problems to the level appropriate for finding the root cause and implementing corrective measures to prevent reoccurrence.

By Direction:

-Hershel Petty

Date:

April 27, 2017

## **1 Scope**

Gorilla Circuits is the manufacturer of Printed Circuit Boards and Full Turn-Key Assembly. The scope of the Quality Management System includes all processes that produce the products and/or services. Section 8.3 is not performed and excluded the scope of operations.

The scope of the Quality Management System does not include processes that are governed by other management systems, such as environmental management, occupational safety and health, or financial management.

## **2 Normative References**

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9001:2015, Quality management systems – Fundamentals and vocabulary

## **3 Terms and Definitions**

For the purpose of this document, the terms and definitions given in ISO 9001:2015 apply.

## **4 Context of the Organization**

### **4.1 Understanding the organization and its context**

Management will periodically identify and evaluate internal and external factors that have an impact on our ability to meet or exceed the expectations of our Quality Management System and the strategic direction of the organization. These factors will be recorded on the QS-FM-080 “Context of the Organization” (sheet 1). These factors and others reviewed during Management Reviews to determine if our Mission and Vision statements need to be realigned to current business conditions and strategy.

### **4.2 Understanding the needs and expectations of the interested parties**

Management has established a list of interested parties that can affect or potentially be affected by our operation. The list (QS-FM-080 sheet 2) will be reviewed during Management reviews and periodically as necessary and revised as required to ensure the QMS is supporting their expectations or requirements. This documented information will be retained for a period of time detailed in the OP-16.

### **4.3 Determining the scope of the quality management system**

Gorilla Circuits is the manufacturer of Printed Circuits Boards and Full Turn-Key Assemblies. The scope of the Quality Management System includes all processes that produce the products and /or services, address internal & external issues as defined in the context of the organization, and requirements and expectations of identified interested parties. Section 8.3 is not done.

The scope of the Quality Management system does not include the processes that are governed by other management systems, such as environmental management, occupational safety, or financial management.

### **4.4 Quality management system and its processes**

Gorilla Circuits has established a Quality Management System (QMS) as a means of meeting the Quality Policy, achieving the Quality Objectives, and ensuring that products and/or services conform to customer requirements. The Quality Management System is continually improved for effectiveness and meets ISO 9001 requirements.

In effect, each Department Manager/Supervisor has the responsibility to align his/her department with the Quality System Manual, Quality Policy and top-level Quality Objectives. Level II Operating Procedures accomplishes this alignment and related work instructions accomplish this alignment.

#### **4.4.1**

Management has established, implemented, maintains, and continually improves the QMS, including all processes needed and their interaction to the International Standard.

Management has determined the processes needed for the QMS and their application and shall:

- a) Determine inputs for each process and the outputs expected
- b) Determine the sequence of the processes and their interaction
- c) Determine and apply criteria necessary to ensure effective operation and control of the processes
- d) Determine and provide resources needed for the processes.
- e) Assign responsibility and authority for the processes
- f) Address and risks and opportunities determined in accordance to section 6

- g) Evaluate the processes and implement changes to ensure they achieve intended results
- h) Make improvements to the processes and QMS as appropriate.

Reference: Process Interaction Map in Appendix B of the Quality Manual, QS-FM-080 (Sheet 3) Process Matrix,

## **4.4.2**

Documented procedures and related documentation that detail the processes of the Quality Management System have been implemented and are continually maintained and controlled by the Document Control function. Current revisions are available and stored in the QMS software. Each employee of the organization is assigned a user name and password to access documented procedures, forms, or logs.

Documented information (may include WI, travelers, forms, logs, etc.) is scanned and electronically retained in accordance to OP-16 "Documented Information Retention Matrix" to demonstrate processes are being carried out as planned.

## **5 Leadership**

### **5.1 Leadership and commitment**

#### **5.1.1 General**

Gorilla Management Team takes responsibility to continually improve the QMS effectiveness by communicating to the organization the importance of following the established QMS and by establishing the Quality Policy and objectives that align to the context and strategic direction of the organization. They also ensure the availability of necessary resources to promote and support integration of the QMS into normal business operations. Quality requirements are integrated into the process procedures as a means to promote continual improvement and supporting contributions to the effectiveness of the QMS. Management will continually review resource requirements to ensure they are available to support management roles and the effectiveness of the QMS. A process map has been established to show the interaction of the processes as a means to understand the associated risks and their effect on other processes.

Senior Management is defined by the President and VP of Operations and their staff.

The President and VP coordinate and participate in monthly employee meetings, daily workflow updates, weekly customer feedback reviews, monthly management meetings, and Management Review meeting(s) to ensure the QMS is meeting its intended results.

### **5.1.2 Customer Focus**

Gorilla's management team strives to continually improve its effectiveness by communicating to the organization the importance of understanding and meeting customer, statutory and regulatory requirements (if ever required).

Management Team ensures that customer needs and expectations are determined, then converted into requirements and met, and risk and opportunities are identified with the aim of achieving customer satisfaction.

Reference: Procedures OP-72 "Contract Review" and OP-82 "Customer Satisfaction - Measurement and Monitoring" are available in electronic media maintained by Document Control

### **5.2 Quality Policy**

**GORILLA CIRCUITS**  
**Quality Policy**

*We are committed to meeting our customer's requirements and building a quality product. We accomplish this by:*

- \*Product Planning*
- \*Process Planning and Control*
- \*Open Communication*
- \*Continual Improvement*

#### **5.2.1 Establish the quality policy**

Management Team has ensured that the Quality Policy is appropriate to the purpose of the context of the organization, and includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS. Furthermore, management has ensured this policy provides a framework for establishing and reviewing quality objectives and is communicated, understood by the organization and is reviewed for continuing suitability.

#### **5.2.2 Communicating the quality policy**

The Quality Policy is posted in departments and on the quality monitors located throughout the facility. Employees are randomly queried on the quality policy and what it means to them and the organization.

### **5.3 Organizational roles, responsibilities and authorities**

To ensure effective administration of the Quality Management System, responsibilities and authorities have been defined and communicated within the organization. A Management Representative has been designated; effective internal communications have been implemented; and documented information is effectively controlled. The primary method of communicating responsibilities and authority to relevant levels of the organization is through Quality Management System documentation. Quality procedures and work instructions define roles, responsibilities and authorities. The following are the ISO Element Responsibilities:

<b>4</b>	<b>Context of the Organization</b>	<b>Responsible and Authority</b>
4.1	Understanding the organization and context	Management Team
4.2	Understanding the needs and expectations of interested parties	Management Team
4.3	Determining the scope of the QMS	President
4.4	QMS and it's processes	Quality
<b>5</b>	<b>Leadership</b>	
5.1	Leadership & commitment	President
5.2	Quality Policy	President
5.3	Organizational Roles, Responsibility, and authorities	Director of Quality
<b>6</b>	<b>Planning</b>	
6.1	Actions to address risks and opportunities	Management Team
6.2	Quality objectives and planning to achieve	Management Team
6.3	Planning of changes	Management Team
<b>7</b>	<b>Support</b>	
7.1	Resources	Management Team
7.2	Competence	Engineering
7.3	Awareness	Quality
7.4	Communication	Manufacturing
7.5	Documentation information	Engineering and Quality
<b>8</b>	<b>Operation</b>	
8.1	Organizational planning and control	Management Team
8.2	Requirements for products or services	Sales, Engineering, Quality
8.3	Design and development of products	N/A
8.4	Control of externally provided processes, products, or services	Purchasing, Manufacturing, & Quality
8.5	Production and service provisions	GM Assembly & Quality
8.6	Release of products and services	Quality
8.7	Control of non-conforming outputs	Manufacturing & Quality

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<b>9</b>	<b>Performance Evaluations</b>	
9.1	Monitoring, measuring, analysis, & evaluation	Engineering & Quality
9.2	Internal Audits	Quality
9.3	Management Review	Quality
<b>10</b>	<b>Improvement</b>	
10.1	General	Engineering
10.2	Non-Conformity and corrective actions	Quality & Engineering
10.3	Continual Improvement	Engineering & Quality

The Director of Quality is the Management Representative for the Quality Management System (QMS). As a member of management, irrespective of other responsibilities, he has the authority to ensure that the system is implemented and maintained in accordance with ISO 9001 requirements. The Director of Quality reports to Management Team on the performance of the QMS, including needs for improvement and for ensuring the promotion of awareness of customer requirements throughout the organization. In addition, the Director of Quality has the responsibility to serve as the liaison with external parties (e.g. Registrar, Customers, Suppliers, etc.) on matters relating to the QMS and ensure the integrity of the QMS after planned and implemented changes.

## **6 Planning**

### **6.1 Actions to address risks and opportunities**

#### **6.1.1**

Management will consider factors related to the context of the organization and interested parties to determine risks and opportunities that need to be addresses to ensure the QMS can achieve the intended goals, enhance desirable effects, prevent or reduce undesirable effects, and demonstrate improvement

The risks are recorded on QS-FM-080 (Sheet 4) and retained for reference during Management review meetings and as necessary.

#### **6.1.2 Actions to address these risks and opportunities**

Actions to address the identified risks are developed taking into account the severity of the risk, the impact on the context of the organization, the effect on interested parties, results of corrective actions, analysis and evaluation of the action, and its impact on Quality of the finished product. Actions may be started in the form of a corrective action per QS-WI-190 "Corrective Actions WI".

Actions are monitored for effectiveness and risks are will be reassessed and updated on the risk assessment forms (QS-FM-080 sheet 4).

### **6.2 Quality objectives and planning to achieve them**

### **6.2.1 Establish quality objectives**

Management Team is responsible for establishing Quality Objectives, including those needed to meet requirements for product and/or services and are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy in the effort to enhance customer satisfaction and support the strategic direction of the organization. The results will be reviewed at the monthly management meeting and re-evaluated and updated as necessary during the management review meeting. The results will be posted on the company monitors for employees. The quality objectives are documented in OP-ML-001 "Objective & Targets".

Reference: Procedure OP-51 "Establishing Objective & Targets and Continual Improvement" available in electronic format maintained by Document Control.

### **6.2.2 Planning to achieve the objectives**

Planning to achieve the goals of the quality objectives will be performed during the management review meetings. The individual objectives are assigned to members of the management team. Each member will evaluate the objective and determine what actions and resources are necessary to achieve the goal and when they will have completed the actions. The results of the quality objectives are monitored for achievement of the goal during the monthly management meeting and during the management review meeting.

### **6.3 Planning of changes**

Planning for changes to processes, equipment, or facilities will be performed in a controlled manner (following OP-41A "Change Control WI") to ensure the integrity of the QMS is maintained during the transition. Changes will be documented and completion of QS-FM-030 "Request for Change" form will be completed by all interested parties and departments to evaluate the impact and any effect to maintaining the requirements of the QMS.

Documentation information will be created or modified as required (per OP-41 "Change Control" )and appropriate training and certification will be implemented.

Reference: Procedure OP-61 "Training Documentation" , OP-62 "Training Review and Planning", and QS-WI-045 "Certification / Decertification" are available in electronic format maintained by Document Control.

## **7 Support**

### **7.1 Resources**

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### **7.1.1 General**

Management determines and provides resources needed for the establishment, implementation, maintenance, & continual improvement of the QMS. During monthly management meetings management discusses and determines capabilities and constraints on internal resources (such as people, equipment, facilities, etc.) and external providers (equipment suppliers, outside services, agencies, etc)

### **7.1.2 People**

Management determines, and provides people necessary for the effective implementation of the QMS and for the operation and control of the process. Additional meetings to review each department's personnel coverage and training status is performed twice per month.

### **7.1.3 Infrastructure**

Management identifies, provides, and maintains the infrastructure needed to achieve the conformity of product, including buildings, workspace and associated utilities; process equipment, both hardware and software; and supporting services such as transport or communication, as applicable. Preventive maintenance is performed in accordance to OP-713.

Resources (that include people, equipment, facilities, etc.) are discussed and reviewed during the monthly management meeting.

### **7.1.4 Environment for the operation of process**

Management identifies and manages the human and physical factors of the work environment needed to achieve conformity of product. These include Temperature & Humidity, safety hazards, lighting, noise, housekeeping, employee behavior, and morale. These factors are reviewed during monthly management meetings or on an as needed basis.

### **7.1.5 Monitoring and measuring resources**

#### **7.1.5.1 General**

Management identifies the monitoring and measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements. Measuring and monitoring processes are followed to ensure that monitoring and measurement is controlled to ensure that measurement capability is consistent with the measurement requirements. Measurement tools are evaluated for appropriateness for the intended measurement purpose.

All documented information (including certifications, risk assessment, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

### **7.1.5.2 Measurement traceability**

Where applicable and to ensure valid results, measuring and monitoring devices are calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards. Where international or national standards do not exist, the basis used for calibration is recorded. Equipment may be adjusted or re-adjusted as necessary, be identified to enable the calibration status be determined, be safeguarded from adjustments that would invalidate the measurement result, and be protected from damage and deterioration during handling, maintenance and storage. The calibration and verification results of measuring and monitoring devices are recorded. Certificates of Calibration reports for these calibrations will be retained for the life of the device (See OP-16 “Documented Information Retention Matrix”). An electronic spreadsheet is maintained to summarize the current calibration status and certificates of tools and equipment.

When measuring and monitoring devices are found to be out of calibration, the previous results are re-assessed (using QS-FM-430 “Calibration Risk Assessment Report”) to determine the effect to the Quality of products processed and corrective action taken, as required.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to the initial use and reconfirmed as necessary.

All documented information (including certifications, risk assessment, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

Reference: Procedure OP-711 “Gage Calibration” is available in electronic format maintained by Document Control.

### **7.1.6 Organizational knowledge**

Engineering maintains guidelines that define the specific manufacturing parameters that are manufactured under the current set of work instructions. Additional knowledge obtained thru failure analysis, operator input, equipment improvements, interaction with operators, suppliers, etc. will trigger evaluation of this knowledge and possibly additions or modifications to these guidelines. Process sequences and special instructions not detailed in work instructions are programmed into the traveler generation software that will be printed on process plan travelers.

## **7.2 Competence**

Management identifies the competency needs for personnel performing activities affecting quality; provides training to satisfy these needs; and evaluates the effectiveness of the training provided. Management also ensures that employees are aware of the relevance and importance and how they contribute to the achievement of the Quality Objectives.

Reference: Procedure OP-61 “Training Documentation” , OP-62 “Training Review and Planning”, and QS-WI-045 “Certification / Decertification” are available in electronic format maintained by Document Control.

All relevant documented information (including certifications, training records, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

## **7.3 Awareness**

Each employee that affects or potentially can affect the quality of the finished product is educated on the established QMS. They are advised of their responsibility and obligation to follow the established work instructions and the impact deviations from the established procedures can have on the finished product quality, customers, the company, and themselves. Documented Information of the employees acknowledgement of awareness of the QMS is be maintained in the employee files.

Reference: QS-FM-140 “QMS Awareness Form”

## **7.4 Communication**

Internal Communication relevant to the QMS within the organization can be between upper management, mid-management, supervisors, operators, technicians, & maintenance. It may be in response to normal reporting requirements, periodic meetings, responses to potential or real quality issues, equipment issues, or other issues that could impact the QMS. It can be in form of direct conversations, written documentation, emails, meetings, postings, monitors, memos, etc.

Reference OP-52 (Internal Communication)

External Communication relevant to the QMS typically include (but not limited to) customers, & suppliers. Sales, Front-end engineering, and quality have primary contact with the customers. Customer communication is typically in response to quoting, delivery status, engineering questions and support, and quality issues or concerns. Purchasing, Quality, Engineers, and Operations have primary contact with suppliers. Supplier communication is typically in response to order placement, delivery schedules, product offerings, processing information, and responses to quality issues.

Reference OP-714 "Customer Issues" and OP-72 is available in electronic format and maintained by Document Control.

## **7.5 Documented Information**

### **7.5.1 General**

The QMS will include documented information that includes requirements by the International Standard and other relevant documents deemed necessary (as detailed in the OP-16 "Documented Information Retention Matrix") for the effectiveness of the QMS.

### **7.5.2 Creating and updating**

When documented information is created or updated, document control will ensure there are unique identifiers and descriptions for each document, they are in a usable format and media, and have been reviewed and approved before use. The documented information must also be suitable and adequate for the function it will be used.

Reference: OP-41 "Document Writing, Revision and Implementation" , QS-WI-106 "Document Change Notification",

### **7.5.3 Control of documented information**

#### **7.5.3.1**

Documented information required by the QMS and the International Standard shall be available and suitable for use and protected from improper access or use and loss.

Reference: Procedure OP-42 "Documented Information Control" and OP-16 "Documented Information Retention Matrix" are available in electronic format maintained by Document Control.

#### **7.5.3.2**

Documented information shall be controlled to ensure it is distributed, accessible, retrievable and of use for the process. It must also be stored and preserved, changes must be controlled (e.g. revisions), and retained and dispositioned as required.

Current revisions of all WI, Forms, and logs are available for access by authorized employees thru the Qpulse QMS software. User names and passwords have been assigned to control access to these documents. Special permissions are granted only to

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assigned Quality personnel to allow implementation of revisions, additions, and deletions to the Document Register.

Documented information is retained as detailed in OP-16 "Documented Information Retention Matrix".

Changes are controlled thru QS-WI-106 "Document Change Notice" work instruction, OP-41 "Document Writing, Revision, and Implementation", and OP-42 "Documented Information Control".

## **8 Operation**

### **8.1 Operational planning and control**

Gorilla will plan, implement, and control the processes identified in section 4.4 that are needed for the manufacturing of the products and to implement actions determined in clause 6. We will do this by determining the requirements, establishing criteria for the processes and acceptance of products, determining resources needed comply with the product requirements, controlling the processes, maintaining and retaining documented information that shows the processes were carried out and the product was complaint. All planned changes to the processes, QMS, documented information is reviewed to mitigate any negative effects of the change.

Outsourced processes will be monitored and product inspected prior to re-insertion into the process flow.

All relevant documented information will be retained in accordance to OP-16 "Documented Information Retention Matrix"

Reference: Procedures and/or Work Instructions are available in electronic media maintained by Document Control.

### **8.2 Requirements for products or services**

#### **8.2.1 Customer communication**

Gorilla Circuits determines and implements effective arrangements for communicating with customers in relation to product information, an inquiry, contracts or order handling (OP-72), including amendments and customer feedback. The change order process (SA-WI-001) and customer service staff ensures ongoing communications and resolution of new and/or changing customer requirements. Customer property is received and maintained in accordance to OP-79 "Customer Property". Contingency actions that arise during reviews or as a result of unexpected circumstances will be communicated to the customer in a timely manner.

Reference: Procedure OP-714 "Customer Complaint", OP-82 "Customer Satisfaction Measuring and Monitoring", OP-72, is available in electronic media maintained by Document Control.

## **8.2.2 Determining the requirements for products or services**

Gorilla Circuits has defined and established a process and procedure whereby customer requirements are identified, reviewed, communicated, and recorded. Customer requirements are identified by Contract Review Activities. These include requirements for delivery and post-delivery, requirements not stated by the customer but necessary for specified or intended use, statutory and regulatory requirements and any additional requirements determined by the organization.

## **8.2.3 Review of the requirements for products or services**

### **8.2.3.1**

Reviews of the customer supplied data and requirements is performed a multiple levels. Depending on the level of complexity or special requirements, Engineering, Operations, Manufacturing, Quality, and/or department supervisors may be used to perform a thorough review.

Gorilla Circuits reviews the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer, ensuring that the product requirements are defined and contract requirements differing from those previously expressed are resolved.

This review also ensures that the organization has the ability to meet defined requirements with documented information that is maintained.

Where the customer provides no documented statement of requirements, Gorilla Circuits confirms the customer requirements before acceptance. Where products requirements are changed, the change order process ensures that new and/or changing requirements are reviewed before a commitment to supply a product and/or service is provided to the customer.

All relevant documented information will be retained in accordance to OP-16 (Documented Information Retention Matrix)

Reference: Procedure OP-72 "Contract Review" is available in electronic media maintained by Document Control.

### **8.2.3.2**

Copies of the contract review are scanned and electronically archived for reference. The documented information can include some or all of the following: Purchase order, Sales order form, Data review forms (SA-FM-040), Planning worksheet, emails, etc.

All related documented information (including Purchase orders, sales order form, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

## **8.2.4 Changes to the requirements for the products or services**

Changes initiated by the customer are processed through the “Change Order Work Instructions” (SA-WI-001). Other changes resulting from identification of issues or discrepancies during planning / manufacturing are communicated with the customer and recorded on the traveler or CAM sheet. These documents are scanned and electronically archived.

## **8.3 Design & development of products or services**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.1 General**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.2 Design and developing plan**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.3 Design and development inputs**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.4 Design and development controls**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.5 Design and development outputs**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

### **8.3.6 Design and development changes**

This Quality System Element is not applicable to Gorilla Circuits. This sub-clause is included to align the clause numbering scheme with that of ANSI/ISO/ASQ Q9001.

## **8.4 Control of externally provided processes, products, and service**

### **8.4.1 General**

All external processes, products, and services must conform to the requirements. The criteria for the evaluation, selection, monitoring of performance, and periodic evaluations of external suppliers providers will be based on the ability to provide processes or product in accordance to the requirements.

Controls will be applied to external providers of processes, products, or services when they are intended for incorporation in our product, provided directly to our customer on our behalf, or as a result of a management decision.

The documented information shall be retained in accordance with OP-16 “documented Information Retention Matrix”

Reference: OP-76 “Supplier Evaluation”, PR-FM-002 “Supplier Survey Form”,

### **8.4.2 Type and extent of control**

Gorilla will ensure that externally provided processes, products, or services do not adversely affect our ability to consistently deliver product to our customer. All external processes will be within the control of the QMS. The controls applied to the external provider and the acceptability of the output will be defined by Gorilla. Consideration will be given to the potential impact the external provider can have on ability to meet customer and any applicable statutory and regulatory requirements as well as the effectiveness of the controls applied to the provider. Gorilla Circuits has established and implemented the inspection (QC-WI-200) or other activities necessary for ensuring that purchased products or services meets specified requirements.

### **8.4.3 Information for external providers**

The Purchase document will detail exactly what product or service is required from the supplier. This may include product or service requested, quantity, date needed, delivery instructions, price, billing terms, acceptability criteria, deliverables, process certification requirements, contact information, etc. The documented information of the request will be retained.

Any outside service product will be inspected (QC-WI-200) prior to releasing back into the process flow.

## **8.5 Production and service provisions**

### **8.5.1 Control of production and service provision**

Management plans and executes production provision under controlled conditions.

Controlled conditions include, but are not limited to;

- The availability of information that describes the characteristics of the product and the results to be achieved (including travelers, prints, data files, industry standards, customer specifications, etc.)
- The availability and use of monitoring and measurement processes and devices at critical stages to ensure acceptance criteria has been met.
- The availability of work instructions (Accessible in Qpulse)
- The use of suitable equipment and facilities to perform processes.
- Properly trained operators to perform the process tasks
- The implementation of release, delivery and post-delivery activities,
- The accountability for all product during production (e.g. parts quantities, split orders, nonconforming product to account that scrap parts have been destroyed, NCMR forms)
- The validation and revalidation where the resulting output cannot be verified.
- The evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized, (process gates signed off by operators)
- The provision for prevention, detection, and removal of foreign objects,(6S program)
- Daily shift pass down meetings
- Properly trained operators to perform the tasks

The service provision Quality System Element is not applicable to Gorilla Circuits.

### **8.5.2 Identification and traceability**

Management identifies the product by suitable means throughout production and service operations. All products have a unique job number added to process panels of the lot to identify and segregate them for similar product. Individual units within the panels may be marked with a unique code to further identify the product after shipment. These codes are recorded on the process traveler. The status of the product is identified with respect to measurement and monitoring requirements.

All documented information (including travelers, CofCs, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

Reference: Procedure OP-78 “Product Traceability and Identification” is available in electronic media maintained by Document Control.

### **8.5.3 Property belonging to customers or external providers**

Gorilla Circuits exercises care with customer and/or government property while it is under our control or being used. Management ensures the identification, verification, protection, and safeguard of customer property provided for use or incorporation into the product. Any customer property lost, damaged, or otherwise found to be unsuitable for use is recorded and reported to customer. Customer property can include intellectual property. All documented information (including data files, fab drawing, etc.) will be retained in accordance to OP-16 (Documented Information Retention Matrix)

Reference: Procedure OP-79 “Control of Customer Supplied Material” is available in electronic media maintained by Document Control.

### **8.5.4 Preservation**

Management preserves conformity of product with customer requirements during internal processing and delivery to the intended destination. This includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product or service.

- Cleaning,
- Prevention, detection and removal of foreign objects,
- Special handling for sensitive products
- Marking and labeling including safety warnings,
- Shelf life control and stock rotation,
- Special handling for hazardous materials.

Individual work instructions address handling protocols for each department or process.

Reference: Procedure OP-710 “Preservation of Product” and OP-712 “Shipping” are available in electronic media maintained by Document Control.

### **8.5.5 Post-delivery activities**

Any Post-delivery activities will be defined and agreed upon during the data review, quoting, and contract review stages.

### **8.5.6 Control of changes**

Changes to a process to evaluate the effectiveness of the change or facilitate immediate changes to a process are controlled using QS-WI-110 “Process Change Notice WI”. PCNs need to be dispositioned before the expiration date. The evaluation of the PCN can

result in a permanent change to the process instructions that will be process in accordance to QS-WI-105 “Document Change Notification WI”

Authorized personnel for approving changes to production processes are identified as the Management, Engineering, and TRB Team as defined in the Gorilla Organizational Chart.(QS-CH-100).

All relevant documented information will be retained in accordance with OP-16 “Documented Information Retention Matrix”

## **8.6 Release of products and services**

Management measures and monitors the characteristics of the product to verify that requirements for the product are met. Measuring and monitoring is carried out at appropriate stages of the manufacturing process in accordance to controlled process work instructions. Evidence of conformity with the acceptance criteria is documented, and documented information indicates the authority responsible for release of product. Product release and service delivery does not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by a relevant authority or the customer.

Gorilla Circuits will retain documented information (In accordance to Op-16) for the release of products that include evidence of conformity to the requirements and the Person(s) authorizing the release of the product

Reference: Procedure OP-84 “Receiving Inspection”, OP-85 “In-Process Inspection”, OP-86 “Final Inspection”, and OP-81 “Statistical Techniques” are available by electronic and hard media maintained by Document Control.

## **8.7 Control of non-conforming outputs**

### **8.7.1**

Gorilla Circuits ensures that product which does not conform to product requirements are identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in documented procedures.

Gorilla Circuits deals with nonconforming product by taking action to eliminate the detected nonconformity, by:

- Appropriate action to eliminate the nonconformity,
- Disposition of the nonconforming material,
- Taking action to control the material, precluding its original use

- Taking appropriate action when nonconforming product is detected after delivery,
- Taking actions to contain the effect on other processes or products.

Products and services delivered to Gorilla Circuits customers must conform to the specified requirements derived from regulatory requirements, performance standards, and contract specifications. When a product or service cannot fulfill the specified requirements, it is nonconforming. Nonconforming product is corrected and subject to re-verification after correction to demonstrate conformity. When nonconforming product is detected after delivery or use has started, Gorilla Circuits takes action appropriate to the effects, or potential effects of the nonconformity.

Reference: Procedure “Non-conforming Product Work Instructions” QS-WI-185 is in electronic media in Q-Pulse.

### **8.7.2**

In the case where Non-conforming product is identified by the customer, the customer complaint and RMA WI (QC-WI-005) will be followed to establish and record the issue and start the investigation and disposition of the product.

All related documented information (may include emails, reports, NCMR, travelers, etc.) will be retained in accordance to OP-16 “Documented Information Retention Matrix”

## **9 Performance Monitoring**

### **9.1 Monitoring, measuring, analysis, and evaluation**

#### **9.1.1 General**

Management defines, what will be monitored and measured, the methods, analysis & evaluation needed for valid results, when monitoring and measuring will be performed, and when the results will be analyzed and evaluated. Management will evaluate the performance of the QMS and retain appropriate documented information (in accordance to OP-16) to support their findings.

#### **9.1.2 Customer satisfaction**

Gorilla Circuits monitors information relating to customer perception as to whether the organization has met customer requirements. Customer satisfaction and/or dissatisfaction are tracked as one of the measurements of performance of the Quality Management System. The primary method for obtaining customer satisfaction and/or dissatisfaction data is via customer surveys. The customer satisfaction and/or dissatisfaction data is compiled

and subsequently used as an input for the Management Review. All related documented information is retained in accordance to OP-16.

Reference: Procedure OP-82 “Customer Satisfaction-Measurement and Monitoring” is available in electronic media maintained by Document Control.

### **9.1.3 Analysis and Evaluation**

The Quality Management System includes processes to collect and analyze data to determine the suitability and effectiveness of the Quality Management System, and to evaluate where continual improvement can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to customer satisfaction; conformity to product requirements; characteristics and trends of processes and products including opportunities for preventive action and suppliers.

Reference: Procedure OP-81 “Statistical Techniques” is available in electronic media maintained by Document Control.

## **9.2 Internal Audits**

### **9.2.1**

Quality Assurance conducts periodic internal audits to determine whether the Quality Management System has been effectively implemented and maintained in accordance with ISO 9001 Standard requirements and to QMS documentation requirements. Internal audits are performed to ensure that the QMS is effectively implemented and maintained.

Reference: Procedure OP-83 “Internal Audits” is available in electronic media maintained by Document Control.

### **9.2.2**

Audits are planned based on the status and importance of the activities to be audited as well as previous audit results

Audit criteria, scope, frequencies, and methodologies are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process, as auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining documented information are defined in documented procedures. Management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verifications of the actions taken and the reporting of verification results.

Relevant documented information will be retained in accordance to OP-16 “documented information Retention Matrix” as evidence of the audit program and the results

Reference: Procedure OP-83 “Internal Audits” is available in electronic media maintained by Document Control.

## **9.3 Management Review**

### **9.3.1 General**

Management Team conducts a management review of the Quality Management System (QMS) at least once in each calendar year. Additional management reviews may be held, as required to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

### **9.3.2 Management review inputs**

Reports generated by the Management Representative are used as a primary input to determine the effectiveness of the Quality Management System. The Management Review Worksheet details relevant inputs to be discussed during the review.

Reference: QS-FM-004 “Management Review Worksheet”

### **9.3.3 Management review outputs**

The output from the management review includes any opportunities for improvement, need for changes to the QMS, and resource needs.

Documented information from management reviews are retained in accordance to OP-16 “Documented Information Retention Matrix”

Reference: Procedure OP53 “Management Review and Analysis of Data” is available in electronic media maintained by Document Control.

## **10 Improvement**

### **10.1 General**

The management team shall identify and select opportunities for improvement and implement actions to meet customer requirements and improve customer satisfaction. This includes improving products to meet current requirements and needs and expectations in the future, correcting, preventing, or reducing undesired results, and improving the performance and effectiveness of the QMS.

The Quality Policy, quality objectives, audit results, analysis of data, corrective, and management review facilitate continual improvement of the Quality Management System.

## **10.2 Non-conformity and corrective actions**

### **10.2.1**

When a non-conformity occurs, (including customer complaints) Gorilla Circuits will:

- a) React to the non-conformity by taking action to control and correct it and deal with the consequences.
- b) Evaluate the need for action(s) to eliminate the cause(s) of the non-conformity, in order
  - 1) Reviewing and analysis of the non-conformity
  - 2) Determine cause of the non-conformity
  - 3) Determine if similar nonconformities exist or could occur
- c) Implement any action(s) needed
- d) Review the effectiveness of any corrective action and detail how it was determined
- e) Update risks and opportunities determined during planning
- f) Make changes to the QMS, if necessary

Corrective action(s) shall be appropriate to the effects of the non-conformity.

### **10.2.2**

All documented information related to the nonconformity will be retained in accordance to OP-16 "Documented Information Retention Matrix". This includes the nature of the non-conformity and actions taken, and results of corrective actions.

## **10.3 Continual improvement**

Management plans and manages the processes necessary for the continual improvement of the Quality Management System. The Quality Policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review facilitate continual improvement of the Quality Management System.

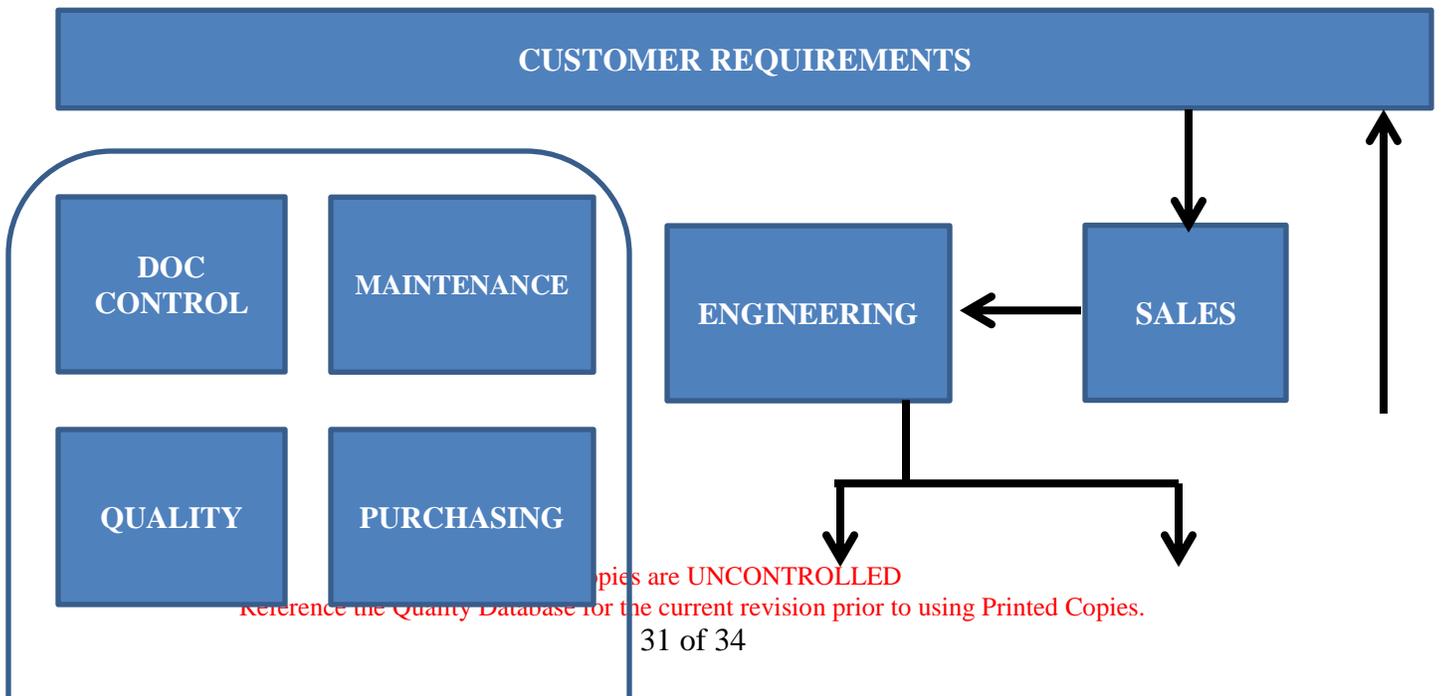
Continual Improvement actions may be derived from the analysis of data, Quality Management System reviews, internal audit findings, customer inputs, and surveillance processes.

Reference: Procedure QS-WI-190 "Corrective Action and Preventive Action" is available in electronic format maintained by Document

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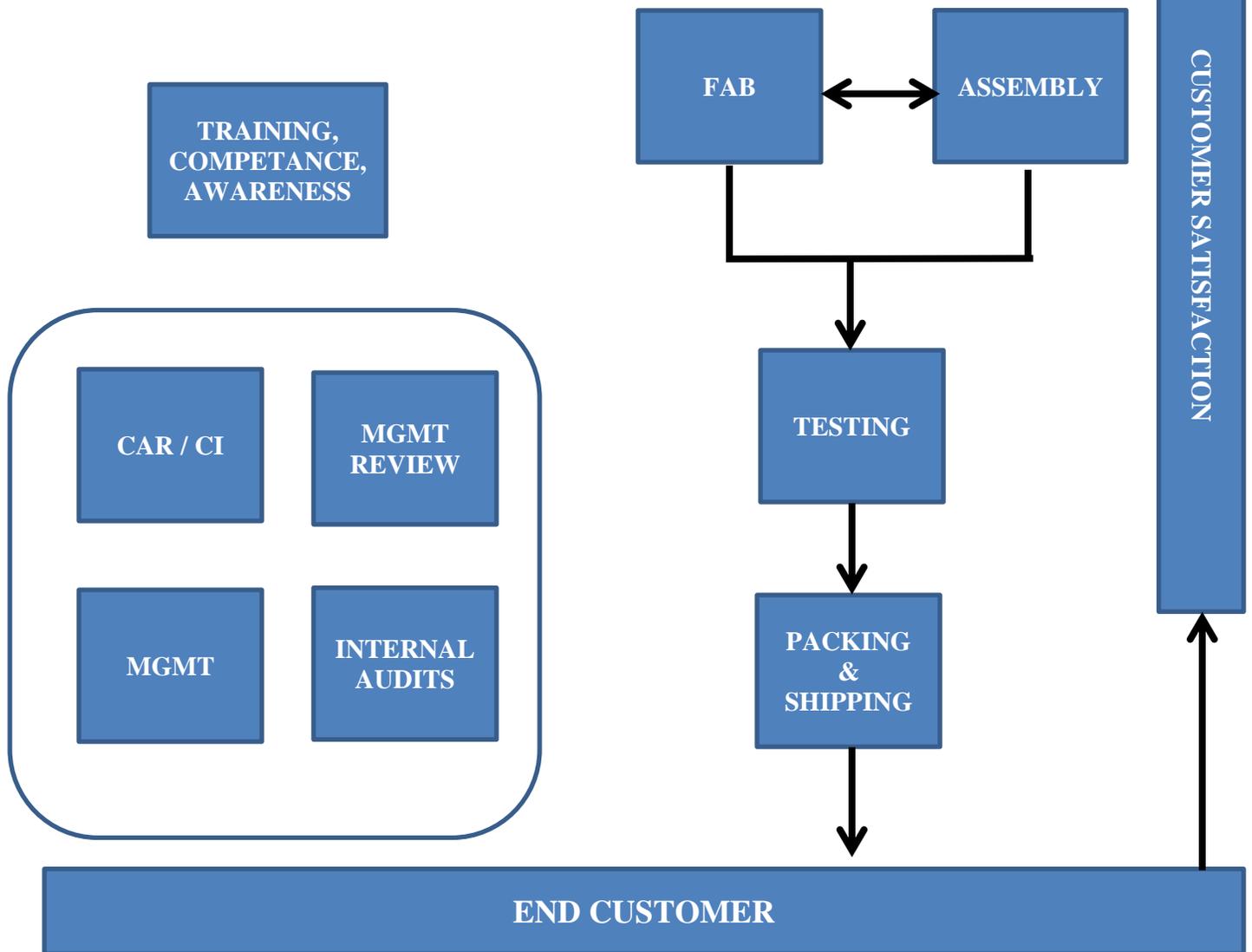
## Appendix B

### PROCESS INTERACTION MAP



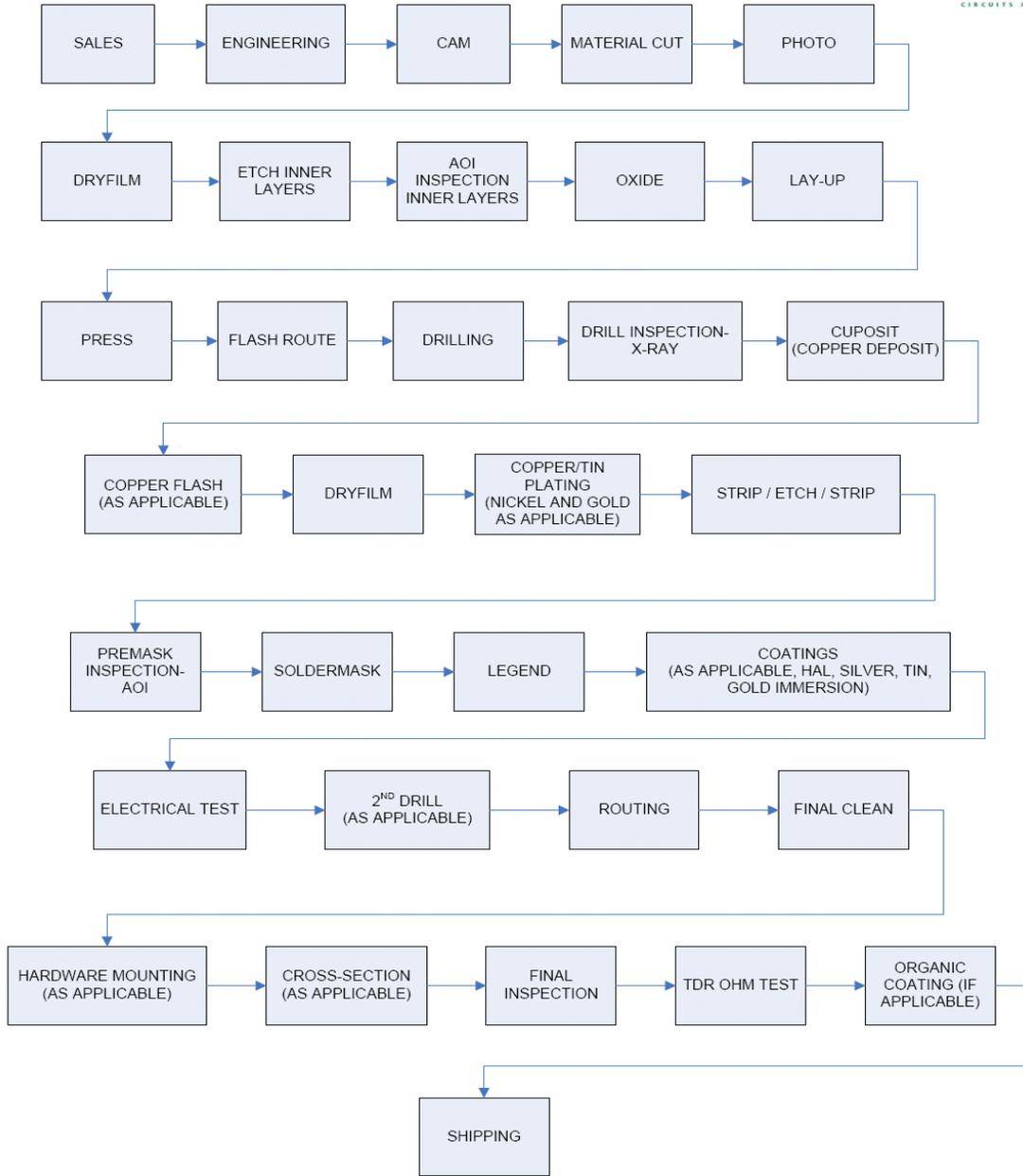
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Reference the Quality Database for the current revision prior to using Printed Copies.



**APPENDIX C -  
TYPICAL FAB & ASSEMBLY PROCESS FLOW CHART**

# Typical Process Flow Chart



## ASSEMBLY

